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APPLI	CATION NO.	FI	LING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09	/522,753	(	03/10/2000	Ronald M. Evans	SALK1510-3	4924
30	542	7590	05/23/2005	•	EXAM	INER
_	OLEY & L		ER		LEFFERS JR.	GERALD G
	.O. BOX 802 AN DIEGO,		138-0278		ART UNIT	PAPER NUMBER
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DATE MAILED: 05/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
	09/522,753	EVANS ET AL.
Office Action Summary	Examiner	Art Unit
	Gerald G. Leffers Jr., PhD	1636
The MAILING DATE of this communication apprention for Reply	ears on the cover sheet with the c	orrespondence address
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply if NO period for reply is specified above, the maximum statutory period who is really experienced by the office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	i6(a). In no event, however, may a reply be time within the statutory minimum of thirty (30) days ill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133).
Status	•	•
1) Responsive to communication(s) filed on 15 Fe	ebruary 2005.	
2a) ☐ This action is <b>FINAL</b> . 2b) ☑ This	action is non-final.	
3) Since this application is in condition for allowan		
closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 45	53 O.G. 213.
Disposition of Claims		
4) Claim(s) 3-5, 9-10, 12-14, 16-25 & 38 is/are pe	nding in the application.	
4a) Of the above claim(s) is/are withdraw	vn from consideration.	
5) Claim(s) <u>9,10,12,13,17 and 38</u> is/are allowed.		
6) Claim(s) <u>4,5,14,16,18,19,21-25</u> is/are rejected.		-
7) Claim(s) 3 and 20 is/are objected to.	alastian maguiromant	
8) Claim(s) are subject to restriction and/or	election requirement.	
Application Papers		
9)☐ The specification is objected to by the Examine	r.	• •
10)☐ The drawing(s) filed on is/are: a)☐ acce		
Applicant may not request that any objection to the c		
Replacement drawing sheet(s) including the correcti  11) The oath or declaration is objected to by the Ex	, -,	
,	arminer. Note the attached Office	Addition former 10 102.
Priority under 35 U.S.C. § 119		
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:		-(d) or (f).
1. Certified copies of the priority documents		on No
<ul><li>2. Certified copies of the priority documents</li><li>3. Copies of the certified copies of the prior</li></ul>		
application from the International Bureau		in this realistic stage
* See the attached detailed Office action for a list		ed.
-	·	
Attachment(s)		
1) Notice of References Cited (PTO-892)	4) Interview Summary	
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)	Paper No(s)/Mail Da 5) Notice of Informal P	atent Application (PTO-152)
Paper No(s)/Mail Date	6) 又 Other: <u>本</u> kibit A	atent Application (PTO-152) (SEARCL Raport SEQ ID No:5)

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#### **DETAILED ACTION**

# Response to Amendment

Receipt is acknowledged of a supplementary response, filed 2/15/2005, in which the response explicitly answered each of the grounds of rejection made in the previous office action mailed on 4/20/2004. In the original response to the previous office action, filed on 8/12/2004, several claims were amended (claims 4, 5, 9, 12, 14, 23 and 25). Claims 3-5, 9-10, 12-14, 16-25 & 38 are pending and under consideration in the instant application.

Any rejection of record not addressed herein is withdrawn. This action is not final as there are new grounds of rejection presented herein that were not necessitated by applicants' amendment of the claims in the response filed on 8/12/2004.

# Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994). The prior application to which the instant application seeks priority is U.S. Application Serial No. 08/522,726, filed 9/1/1995 (now U.S. Patent No. 6,489,441). The '726 application discloses only 3 sequences that correspond to SEQ ID NOS: 1-

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3 of the instant application. Each of the pending claims is directed to an isolated polynucleotide that (i) has a recited percent identity to one of SEQ ID NOS: 4, 6, & 8; or (ii) encodes a polypeptide having a recited percent identity to one of SEQ ID NOS: 5, 7 & 9. The prior application does not disclose these particular sequences. Therefore, the prior application does not provide support for the broadly recited genus of polynucleotides encompassed by the pending claims. Accordingly, the priority date for the pending claims is the filing date of the instant application (3/10/2000).

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4, 19, 21-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al (Nature, October 1995, Vol. 377, No. 6548, pages 454-457; see the entire reference). This is a new rejection.

Chen et al teach the identification and characterization of a transcriptional co-repressor that is an SMRT (i.e. silencing mediator for retinoid and thyroid hormone receptors). The SMRT polypeptide taught by Chen et al is encoded by a polynucleotide sequence that encodes a polypeptide that is ~94% identical to the sequence of SEQ ID NO: 5 (see the attached Exhibit A,

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result #6 for accession number HSU37146). Thus, the polynucleotide sequence taught by Chen et al anticipates the broad genus of polynucleotides encompassed by the instant claims.

Claims 4, 19, 21-22 are rejected under 35 U.S.C. 102(a) as being anticipated by Ordentlich et al (PNAS USA, 16 March 1999, Vol. 96, No. 6, pages 2639-2644; see the entire reference). This is a new rejection.

Ordentlich et al teach unique forms of the human and mouse nuclear receptor corepressor SMRT. In particular, Ordentlich et al teach nucleic acids, described by accession numbers AF113003 & AF113001, that encode polypeptides with 100% & 88.2% identity with SEQ ID NO: 5, respectively (e.g. see results 1 & 3 of the search report provided as Exhibit A).

Claims 4, 19, 21-22 are rejected under 35 U.S.C. 102(a) as being anticipated by Park et al (PNAS USA, 30 March 1999, Vol. 96, No. 7, pages 3519-3524; see the entire reference). This is a new rejection.

Park et al teach the identification of an extended isoform of SMRT termed SMRTe by the authors. In particular, Park et al teach nucleic acids, described by accession numbers AF125672 & AF125671, that encode polypeptides with ~98% and ~82% identity with SEQ ID NO: 5 (e.g. see results 2 & 4 of the search report provided as Exhibit A).

### Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5 & 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new rejection.

Claim 5 is directed to an isolated polynucleotide encoding an SMRT co-repressor, or a peptide portion thereof, where the SMRT co-repressor or peptide portion thereof is capable of mediating the transcriptional silencing of at least one member of the steroid/thyroid hormone superfamily of receptors. The claim then recites the limitation of "... wherein said SMRT corepressor or peptide portion thereof is encoded by a polynucleotide having at least 80% sequence identity with SEQ ID NO: 4". This latter recitation appears to specify that the polynucleotide having at least 80% identity to SEQ ID NO: 4 is a different polynucleotide from the one that is actually claimed. As such, the nucleotide that is actually claimed can be any nucleotide that encodes the same SMRT protein, or portion thereof, that is encoded by the second nucleotide sequence (e.g. the first polynucleotide encodes the SMRT protein, or portion thereof, and which is different from the second polynucleotide because of the degeneracy of the genetic code and/or because the two different polynucleotides comprise additional, different sequences from one another). There does not appear to be support anywhere in the originally filed specification or claims for this formulation. Therefore, the phrase "... wherein said SMRT co-repressor or peptide portion thereof is encoded by a polynucleotide having at least 80% sequence identity with SEQ ID NO: 4" is impermissible NEW MATTER.

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Claims 23-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a new rejection necessitated by applicants' amendment of the claims in the response filed on 8/12/2004.

Claim 23 is directed to a genus of oligonucleotides that are identifiable under "suitable stringency conditions" with respect to other nucleic acid sequences. The term "suitable stringency conditions" is used in the context of an identified oligonucleotide comprising at least 15 nucleotides that hybridizes to a polynucleotide of claim 4, but not to a polynucleotide encoding SEQ ID NO: 11 or to a polynucleotide encoding an amino acid sequence consisting of amino acids 1031 to 2517 of SEQ ID NO: 5. The specification does not define these exact conditions and the skilled artisan has no basis to visualize what these "suitable" conditions might be. Similarly, claim 25 specifies that the oligonucleotide of claim 23 hybridizes under "suitable stringency conditions" to a polynucleotide encoding SEQ ID NO: 5 or SEQ ID NO: 7, but does not hybridize to a polynucleotide encoding SEQ ID NO: 9. Again, the exact hybridization conditions are not described. Thus, the rejected claims comprise a genus of oligonucleotides that must meet very particular hybridization requirements, yet there is no description of the hybridization conditions that will necessarily identify an oligonucleotide having the recited functional activity.

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There does not appear to be any literal or implicit support in the originally filed claims or specification for claiming an isolated oligonucleotide comprising at least 15 nucleotides and having the particular hybridization characteristics recited in the rejected claims. Therefore, the rejected claims comprise impermissible NEW MATTER.

Further, there is no basis for the skilled artisan to predictably envision even a single oligonucleotide sequence that will meet all of the hybridization requirements recited in the rejected claims. Thus, the skilled artisan would not have been able to envision a sufficient number of embodiments to describe the claimed genus of oligonucleotides having very particular binding characteristics.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 5, 14, 16, 18 and 23-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These are new grounds of rejection.

Claim 5 is vague and indefinite in that the metes and bounds of the phrase "... wherein said SMRT co-repressor or peptide portion thereof is encoded by a polynucleotide having at least 80% sequence identity with SEQ ID NO: 4" are unclear. Is the polynucleotide recited in this phrase necessarily the same as the isolated polynucleotide that is being claimed or can it be a second polynucleotide (e.g. a different polynucleotide that encodes the SMRT protein, or portion thereof, and which is different from the claimed polynucleotide because of the degeneracy of the

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genetic code and/or because the two different polynucleotides comprise additional, different sequences from one another)?

Claim 14 recites a "first isolated polynucleotide encoding a SMRT co-repressor" and then recites that the first polynucleotide is selected from a Markush group of different polynucleotides. It is unclear how the nucleotides of part (d) can encode a SMRT co-repressor, or portion thereof, when they are *complementary* to sequences in parts (a)-(c) that actually do encode an SMRT co-repressor. Similarly, claim 16 also recites that the first polynucleotides of part (d) have 80% identity to the *complement* of sequences in parts (a)-(c).

Claim 23 is vague and indefinite in that the metes and bounds of the phrase "suitable stringency conditions" are unclear. The phrase is used in the context of an identified oligonucleotide comprising at least 15 nucleotides that hybridizes to a polynucleotide of claim 4, but not to a polynucleotide encoding SEQ ID NO: 11 or to a polynucleotide encoding an amino acid sequence consisting of amino acids 1031 to 2517 of SEQ ID NO: 5. The specification does not define these exact conditions and the skilled artisan has no basis to visualize what these "suitable" conditions might be.

Similarly, claim 25 specifies that the oligonucleotide of claim 23 hybridizes under "suitable stringency conditions" to a polynucleotide encoding SEQ ID NO: 5 or SEQ ID NO: 7, but does not hybridize to a polynucleotide encoding SEQ ID NO: 9.

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### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G. Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gerald G Leffers Jr., PhD Primary Examiner

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ExhibitH	09/522,753 Page 1	Applicant Copy
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